

Appln. No. 09/820,339
Amd. dated April 17, 2007
Reply to Office Action of November 15, 2006

REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. Claim 12 is allowed. Claims 8, 9, 14-18, 25, 27, 30, 31 and 36-41 also presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 8, 9, 15-18, 30, 31 and 36-39 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner states that, in contrast to applicants' arguments on page 9 of the response, the mere "positive" recitation of Hø1-210 is not reasonably equivalent to an "exclusionary proviso [with] basis in the original disclosure", which alternatively must be explicitly stated within the original specification. The examiner further states that the courts have held that negative limitations that exclude compounds do not meet the requirements of 35 U.S.C. §112 because it attempts to claim the invention by excluding what was not invented rather than what was invented, citing *In re Schechter* 98 USPQ 144 (CCPA 1953). This rejection is respectfully traversed.

Before presenting applicants' arguments, it is believed that claim 9 was inadvertently included in this rejection because

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everything recited in claim 9 is allowable in the examiner's indication of allowable claims (claim 12 and claims that are only objected to as being dependent from a rejected base claim).

Turning to applicants' argument, first, there is no prohibition against negative limitations. As stated in MPEP 2173.01:

A fundamental principle contained in **35 U.S.C. 112**, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as ****>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01.<** Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. (emphasis added)

Second, the *In re Schechter* case cited by the examiner is an older case that is no longer representative of the current view of the courts. Indeed, MPEP 2173.05(i) on Negative Limitations states:

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of

35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).

A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). (emphasis added)

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Third, the decision in *In re Johnson* 194 USPQ 196 (CCPA 1977), which is what is currently accepted by the courts and the USPTO, states:

The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

The board indicated that "it is manifestly immaterial" why appellants limited their claims. Though it is true that insufficiency under §112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under §112 arises is immaterial. Quite the contrary. Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."

In short, the positive recitations in the present specification of Hx1-210 and Hx1-210 with one more/additional

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residue do indeed provide adequate written description to excise what applicants are not entitled to from their claimed invention by the use of negative limitations. Such negative limitations, which have basis in the original disclosure only as positive recitations, are permitted and do not constitute new matter.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 36-39 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner states that it remains ambiguous how a "polypeptide tolerogen [that] does not consist of residues 1-210 of SEQ ID NO:2" can also "consist... of amino acid residues 1-210 of SEQ ID NO:2" as recited in (c), which the examiner holds is contradictory. This rejection is respectfully traversed.

This statement that the proviso is inconsistent with the language previously appearing in the claim is not understood. Subpart (c) of claim 36 does not consist of residues 1-210 of SEQ ID NO:2; it only includes 1-210 fused to an additional polypeptide. However, because subparts (a) and (b) of claim 36 are broad enough to read on residues 1-210 or residues 1-210 plus one additional amino acid residue, the alternative provisos are added to claim 36 to exclude these two possibilities from the generic provisions of subparts (a) and (b). In light of the

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clarification above, this rejection is obviated by the amendment to claim 36, which does not raise a new issue because it simply clarifies the alternative provisos and avoids the indefiniteness issue. The same clarifying amendment is made to claim 8. Furthermore, this amendment to the claims does not require a further search because the examiner has already searched the full scope of the claims as amended.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 8, 16-18, 30 and 36-39 have been rejected under 35 U.S.C. §102(b) as being anticipated by Talib et al. (1991, IDS Ref AM). The examiner states that, in contrast to applicants' arguments on pages 10-11 of the response, the additional alternative recitation of "or said sequence and one additional residue" does not obviate the previous claim limitations, because the examiner holds that this recitation only broadens the claims, and limits nothing already recited.

This rejection is obviated by both provisos recited in claims 8 and 36 as clarified by the amendment to the alternative provisos. It is clear from the explanation above with respect to the indefiniteness rejection that the provisos do not broaden the claim but serve to exclude two possibilities, i.e., species, from the generic provisions of subparts (a) and (b) of claim 36 and

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subpart (iv) of claim 8. Accordingly, Talib's disclosure of a polypeptide consisting of residues 1-210 of SEQ ID NO:2 or a polypeptide consisting of SEQ ID NO:2 with an additional residue (Met) at the N-terminus does not anticipate the present claims because Talib's polypeptide(s) is specifically excluded from the claims, which is permitted using negative limitations as discussed above with respect to the §112, first paragraph, written description rejection.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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